191. The method of claim 130, wherein said growth factor controls three-dimensional protein structure and growth.

REMARKS

At the outset, Applicant's attorneys wish to express appreciation for the courtesies extended by Examiner Nicholas Lucchesi during the interview of January 31, 2000. The inventor, Dr. James P. Elia; Assignee's representative, Dr. Jerry W. Bains; and Applicant's attorneys, Charles N. Lovell and Gerald K. White, attended the interview.

Receipt of the Examiner Interview Summary Record prepared by Examiner Lucchesi on January 31, 2001 (Paper No. 12) is acknowledged by Applicant's attorney. Applicant believes that the Examiner's summary is accurate.

It is noted that the Examiner has questioned the completeness of the claim of benefit of Applicant's parent application mentioned in the Oath. It is noted that the Amendment of December 16, 1999, amended the specification to set forth a chain of applications from which Applicant claims benefit under 35 U.S.C. §120. Such chain of applications is further amended in the instant Amendment to delete Application Serial No. 877,132, filed on May 1, 1992. A substitute Declaration, setting forth the same claimed benefit is submitted concurrently with this paper. Such submission should fully respond to the Examiner's objection. It is noted that the address of the inventor, James P. Elia, in the original Declaration was "6621 East Friess Drive,

Phoenix, Arizona 85254". The fact that Mr. Elia's current address is 7364 East Crimson Sky Trail, Scottsdale, Arizona 85262 is reflected in the substitute Declaration.

It is noted that the Examiner will require formal drawings when the application is allowed. Applicant hereby submits formal drawings concurrently in an effort to expedite the potential allowance and grant of the application.

Claims 1-5 stand rejected under 35 U.S.C. §101 as lacking statutory subject matter and lacking patentable utility. In addition, the specification was objected to under the first paragraph of 35 U.S.C. §112 for failing to provide an enabling disclosure. Moreover, claims 1-6 were rejected under the first paragraph of 35 U.S.C. §112 as containing subject matter that would not enable one skilled in the art to make and/or use the invention. Finally, claims 2 and 6 were rejected under the first paragraph of 35 U.S.C. §112 for failing to provide proper basis for the phrase "formation of new blood vessels".

Applicant has canceled claims 1-6, without prejudice to including such or similar claims of a different scope in a subsequent continuation, divisional, or continuation-in-part patent application, and added new claims 7-191. Applicant respectfully submits that the newly presented claims, accompanying remarks, and evidentiary submissions provide sufficient basis for the Examiner to not repeat such rejections and objections for the newly presented claims, and instead, provide sufficient basis for the Examiner to allow such claims.

It is respectfully believed that the rejection of prior claims 1-6 under 35 U.S.C. §101 as being directed to non-statutory subject matter should not be repeated for newly presented claims 7-191. The Examiner stated that "A claim drawn to a non-plant multicellular organism (an organ) or a naturally occurring article which has not been altered is not considered new under 35 U.S.C. §101." Applicant notes that newly presented claims 7-191 (as well as previously rejected claims 1-6) are not drawn to an organism or naturally occurring article. Instead, such claims are drawn to a method of forming a desired soft tissue, a desired soft tissue comprising mesodermal tissue, or a desired blood vessel in the body of a human patient which involves placing a growth factor in the body to form a bud which grows into the desired tissue or vessel. Clearly, no claims of the type mentioned by the Examiner are present in this application; and accordingly, the rejection under 35 U.S.C. §101 should not be repeated. A further indication that claims 7-191 comply with 35 U.S.C. §101 is illustrated by United States Patent Number 5,652,225 to Isner (hereinafter the Isner '225 patent). A copy of this patent was made of record in Applicant's December 16, 1999 response. All claims of the Isner '225 patent are drawn to a method generally similar to that claimed in this application, i.e., the Isner '225 patent claims are directed to inducing the formation of new blood vessels in a desired target tissue in a human host. It is well known that blood vessels are a type of soft tissue and that blood vessels and other organs contain mesodermal tissue.

The Examiner made a further rejection under 35 U.S.C. §101 based upon an alleged lack of utility and under the first paragraph of 35 U.S.C. §112 as non-enabling. The Examiner further stated that the claimed method of creating and growing organs *in vivo* or *in vitro* borders on the incredible to one of ordinary skill in the art. The Examiner then explained that such

rejection might be overcome by submitting evidence, in affidavit form, based upon the results of appropriate scientific tests.

Applicant has carefully considered the Examiner's above helpful suggestions and, as a result, hereby submits declarations of four (4) medical doctors and other evidence from the Isner '225 patent file history (please see the Declaration of Gerald K. White, Applicant's attorney, in this regard) that are believed to fully respond to the Examiner's requirement for scientific evidence that the claimed invention is operable.

Lest there be any doubt that the specification of the instant application as well as each of the parent applications in the chain of co-pending applications relied upon by Applicant under 35 U.S.C. §120 fails to comply with the enabling requirement of the first paragraph of 35 U.S.C. §112, those doubts should be more than satisfied when the specification disclosure is viewed in conjunction with Applicant's evidentiary submissions including the respective Declarations of Drs. Wheeler, Finley, Lorincz, and Meger and copies of two (2) Declarations of Dr. Jeffrey M. Isner contained in the Isner '225 patent file history (please see Declaration of Gerald K. White). The declarations clearly evince that one of ordinary skill in the art would supply details from his/her working knowledge of the art when attempting to practice applicant's disclosed invention. Further, it is clear from the record of the Isner '225 patent that following Applicant's disclosure necessarily and inherently results in the formation of soft tissue, e.g. blood vessels. That the Isner '225 patent teaches employing common angiogenic growth factors and placement techniques for causing the growth of blood vessels in a human host, compels such a conclusion.

Applicant believes that the disclosures at pages 20, 21, 30 and 31 of the instant application, which correspond to disclosures carried forward from each of the parent applications in the chain of co-pending applications relied upon under 35 U.S.C. §120, teach the manner and process of making and using the invention in terms which correspond in scope to the subject matter sought to be patented in newly presented claims 7-191 and thusly satisfy both the description and enablement requirements of 35 U.S.C. §112.

To the extent that the Examiner may possibly consider that the instant specification and the chain of co-pending applications fail to teach details as to the formation of soft tissue, e.g. blood vessels, Applicant believes that the evidentiary submissions in the instant record establish that one of ordinary skill in the art would supply such details from his/her knowledge of the art, primarily because he/she has a working knowledge of the field and the principles intended and, hence, is expected to exercise ordinary resourcefulness in reading the instant claims.

It is respectfully submitted that the Declaration of Dr. Meger clearly demonstrates that the medical placement and activation techniques mentioned in the specification of this application were known to those skilled in the medical arts prior to July 2, 1993 (the effective filing date for Applicant's disclosure) and that one skilled in the art armed with such knowledge would have been able to practice the invention.

Moreover, the respective Declarations of Drs. Wheeler, Finley, and Lorincz conclude that the process of placing a growth factor at a desired site of a human body will predictably produce

a bud that will subsequently grow into soft tissue. Support for such conclusion is supplied by the documents of Exhibit C appended to each Declaration which clearly illustrate the operability of Applicant's process through the results of credible scientific tests conducted by reputable scientists in the medical arts. Such test results collectively provide strong evidence that the claimed invention functions as described in the specification. It is further considered that the number of different authors provides additional evidence that the invention could be practiced by the art with no more than routine experimentation, thus clearly enabling one skilled in the art to make and use the invention. Of special note in the materials appended to these Declarations at Exhibit C is the aforementioned Isner '225 patent.

As indicated in the enclosed Declaration of Gerald K. White, during the prosecution of each of his two patent applications, a declaration was submitted by the inventor, Dr. Jeffrey M. Isner. While they speak for themselves, both declarations provide evidence that Dr. Isner's procedure grew blood vessels on human hosts. The declaration executed by Dr. Isner on December 7, 1995 included a manuscript with test results illustrating that his "method of nucleic acid delivery can and does work in providing angiogenesis." Dr. Isner's declaration of November 18, 1996 included a copy of a reprint from the August 10, 1996 issue of Lancet that reflected work performed by Dr. Isner that promoted angiogenesis on a limb of a 70 year old woman. It thus appears credible that Dr. Isner's procedures lead to angiogenesis; and further, it appears that such conclusion was accepted by the Examiner by the granting of the Isner '225 patent.

Inasmuch as Dr. Elia's invention may utilize common angiogenic growth factors and placement techniques as that of the Isner '225 patent, it is submitted that the above two (2) declarations of Dr. Isner constitute powerful, convincing evidence that the disclosed invention of Dr. Elia is both operable and enabling.

One final point remains. Claims 2 and 6 have been rejected under the first paragraph of 35 U.S.C. §112 as failing to provide antecedent support for the "formation of blood vessels" language recited therein. Initially, Applicant notes that claims 2 and 6 are no longer pending in the application, the subject matter of these claims being carried forward into new claims 130-191. Applicant disagrees that the questioned language lacks descriptive support in the instant application. In particular, see page 44 of the instant application wherein is described growing soft tissues such as arteries. Blood vessels, i.e. arteries, are well known types of soft tissue. Such conclusion is affirmed in Paragraph 5 of the Declarations of Drs. Wheeler, Finley, and Lorincz. Though growing a blood vessel is not described in *ipsis verbis* in the disclosure of parent application Serial Number 87,185, filed July 2, 1993, the formation of "soft tissue in a body of a human patient comprising placing a growth factor in said body to form a bud which grows into said desired soft tissue" is described therein and in each of the parent applications in the chain of co-pending applications from which Applicant is claiming the benefit under 35 U.S.C. §120. Further, each of the applications in said chain beginning with Serial Number 87,185 through the instant application contains the disclosure found at page 20, line 10 through page 21, line 15 and page 30, lines 14 through 22 and page 31, lines 18 through 26 of the instant application. Said disclosures describe employing well known angiogenic growth factors (please see references 1 through 7 of Exhibit C-3 of the above-mentioned three (3) declarations), carriers

and delivery techniques in terms corresponding in scope to the claimed subject matter. The function of the description requirement of 35 U.S.C. §112 is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him. E.g., In re Blaser, 556 F.2d 534, 194 USPQ 122 (CCPA 1977); In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Smith & Hubin, 481 F.2d 910, 178 USPQ 620 (CCPA 1973). To comply with the description requirement, it is not necessary that the application describe the claimed invention in *ipsis verbis*, In re Lukach, 58 CCPA 1233, 442 F.2d 967, 169 USPQ 795 (1971); all that is required is that it reasonably convey to persons skilled in the art that, as of the filing date thereof, the inventor had possession of the subject matter later claimed by him. See In re Driscoll, 562 F.2d 1245, 195 USPQ 434 (CCPA 1977). In the context of the present case, this translates into whether the parent applications provide adequate direction which reasonably leads persons skilled in the art to the later claimed subject matter. See Flynn v. Eardley, 479 F.2d 1393, 178 USPQ 288 (CCPA 1973). By the very nature of this inquiry, each case turns on its own specific facts. See In re Driscoll, supra. Applicant believes that the instant specification satisfies the description requirement of 35 U.S.C. §112 under current law as regards the formation of blood vessels according to the described methodology. Accordingly, for the above reasons, Applicant submits that claims 130-191 drawn to a method for producing blood vessels are not properly rejectable as being in derogation of the description requirement of 35 U.S.C. §112.

In conclusion, Applicant believes that newly added claims 7-191 satisfy the requirements of 35 U.S.C. §101 and the first paragraph of 35 U.S.C. §112 under present law. In Applicant's

opinion, the current law regarding the requirements of 35 U.S.C. §112 are summarized in the following excerpt In re Armbruster, 512 F.2d 676, 185 USPQ 152, at 153 (CCPA, 1975):

> Although appellant's specification describes the invention as broadly as it is claimed, thereby eliminating any issue concerning the description requirement, a specification, which "describes" does not necessarily also "enable" one skilled in the art to make or use the claimed invention. See In re Mayhew, 481 F.2d 1373, 179 USPQ 42 (CCPA 1973). However, this court has made it clear that the Patent and Trademark Office must substantiate its rejection for lack of enablement with reasons. Worth repeating is the following statement from In re Marzocchi, 58 CCPA 1069, 439 F.2d 220, 169 USPQ 367, 369-370 (1971):
>
> > The only relevant concern of the Patent Office under these circumstances should be over the truth of any such assertion. The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.
> >
> > As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt does exist, a rejection for failure to teach how to make and/or use will be proper on that basis; such a rejection can be overcome by suitable proofs indicating that the teaching contained in the specification if truly enabling.
> >
> > ...it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure. [Emphasis in original and footnote deleted.]

Accord, In re Dinh-Nguyen, 492 F.2d 856, 181 USPQ 46 (CCPA 1974); In re Bowen, 492 F.2d 859, 181 USPQ 48 (CCPA 1974).

> Section 112 does not require that a specification convince persons skilled in the art that the assertions therein are correct. In re Robins, 429 F.2d 452, 166 USPQ 552 (CCPA 1970).

For the above-mentioned reasons and supporting evidence, Applicant respectfully submits that the instant application is in condition for allowance, and a notice to such effect is respectfully requested.

Should the Examiner have any questions or require additional information or discussion to place the application in condition for allowance, a phone call to the undersigned attorney would be appreciated.

Respectfully submitted,

Dated: February 14, 2001

Gerald K. White
Reg. No. 26, 611

Attorney for Applicant

GERALD K. WHITE & ASSOCIATES, P.C.
205 W. Randolph Street, Suite 835
Chicago, IL 60606
Phone: (312) 920-0588
Fax: (312) 920-0580
Email: gkwpatlaw@aol.com

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CERTIFICATE OF MAILING

I hereby certify that the attached AMENDMENT was delivered to the Assistant Commissioner for Patents by the undersigned from Arrow Intellectual Property Services, 2001, Jefferson Davis Highway, Suite 602, Arlington, Virginia 22202, by hand carrying said AMENDMENT to Art Unit 3732, Building 2, Second Floor, Attention: Examiner Nicholas D. Lucchesi this 15th day of February, 2001.

Dated: 2/15/01

Ann Rutledge

Printed Name: Ann Rutledge

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